## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.

09/772,445

Applicant Filed

KLEINMAN et al. January 29, 2001

TC/A.U.

1654

Examiner

Ronald T. Niebauer

Docket No.

2600-109

Customer No.

06449

Confirmation No.

1045

## Declaration of Dr. Jo-David Fine Under 37 C.F.R § 1.132

Director of the United States Patent and Trademark Office P.O. Box 1450 Alexandria, Virginia 22313-1450

Dear Sir:

I, Jo-David Fine, M.D., M.P.H., FRCP (London), declare as follows:

- I am Professor of Medicine (Dermatology) and Pediatrics, Vanderbilt University,
   Nashville, Tennessee.
- 2. I have been awarded a Bachelor Science Degree in Chemistry from Yale College, and a M.D. degree (with distinction) from University of Kentucky College of Medicine.
- 3. My post graduate training included an internship in medicine and a junior assistant residency in medicine at Duke University Medical Center, a residency in Dermatology in Massachusetts General Hospital in Boston with a Clinical Fellowship at Harvard University, a Senior Residency in Dermatology at Lahey Clinic Foundation in Boston with a Clinical Fellowship at Harvard University, a Medical Staff Fellowship in Dermatology at the National Institutes of Health, National Cancer Institute, and various faculty positions at the medical schools of the University of Alabama at Birmingham, the University of North Carolina at Chapel Hill, the University of Kentucky, Vanderbilt University, and St. John's Institute of Dermatology at Guy's, King's and St. Thomas' School of Medicine (King's College London, University of London), St. Thomas' Hospital, London

and the Department of Cell & Molecular Pathology at St. John's Institute of Dermatology, London. A copy of my Curriculum Vitae is attached hereto as Exhibit A.

- 4. I have been informed that claims of the above-referenced U.S. patent application have been rejected on the basis of U.S. Patent No. 6,030,948 (Mann), alone, or in combination with other references.
- 5. I have been informed that it is the position of the U.S. Patent and Trademark Office in an Office Action dated April 17, 2008, that Mann teaches a method of applying a composition containing thymosin β4 "to the scalp (claim 8). Prior to application to the scalp, an acid peel (i.e., chemical peel) solution is applied to the scalp and then removed. The removal of the acid peel solution results in the removal of an outer later of skin and results in abrasions/damage/lesions/wounds upon the skin." (emphasis added).
- 6. I have studied U.S. Patent No. 6,030,948 to Mann. For the following reasons, the statement that the acid peel of Mann results in "abrasions/damage/lesions/wounds" on the skin is incorrect.
- 7. Column 10, lines 56-62 of the Mann patent states as follows:

"In the method of this invention, the following steps are performed in the order noted: (1) cleansing the scalp with a cleansing agent; (2) treating the cleansed scalp with a keratin solvent system; (3) applying a topical anesthetic (optional); (4) applying an acid peel solution; (5) applying a hyperactive urea gel formula (optional) and (6) applying a hair regeneration composition."

8. Acid peel systems are described in Step 4 of Mann, column 13, line 19 to column 14, line 11, and in claims 17 and 18 of Mann, as follows:

"Step 4: Acid Peel Systems

Application of the optional fragrance-based topical anesthetic is followed

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by the application of an acid-based system with the composition shown in Table 6. This composition included a series of physiological acids, including citric acid and pyruvic acid, in combination with a surfactant that will enhance penetration and a solubilizing system which also facilitates penetration. The acid peel system is allowed to remain on the scalp for anywhere between 1 minute to 8 hours or more. If the acid peel system is allowed to remain on the scalp for more than about 30 minutes, an occlusive cap may be placed on the head covering the scalp. As used herein, an occlusive cap means any structure, which when placed on the scalp of the head, prevents the acid peel system from leaving the surface of the scalp.

The following Table 10 provides a range of concentrations of ingredients that may be used in the acid peel solution.

#### TABLE 10 ACID PEEL

Citric acid 20.00 Salicylic acid 10.00 Methyl salicylate 10.00 Menthol 1.00 POLYSORBATE-80 3.00 2-Phenoxyethanol 6.00 Pyruvic acid 10.00 TERGITOL 15-S-7 1.00 Methyl nicotinate 0.50 Alcohol SD40 A (190) 23.00 Demineralized water 15.50

The above ingredients are shown in weight percent, and are available from commercial suppliers such as Brooks, Sigma (St. Louis, Mo.) and Aldrich (Milwaukee, Wis.)."

- 9. Claims 17 and 18 of Mann read as follows:
  - "17. The method of claim 8 wherein the acid peel solution comprises at least one physiological acid.
  - 18. The method of claim 17 wherein the physiological acid is citric acid, ascorbic acid or pyruvic acid."
- 10. Acid peels are used for the purpose of skin exfoliation. The primary use of acid peels is to help rid skin surface areas of dead cells and to stimulate cellular proliferation of a new healthy-looking, smoother, more evenly pigmented, and "glowing" skin. Mann's patent describes the use of physiological acids (specific acid peels) to increase skin permeability.
- 11. Claim 17 of the above referenced Mann patent indicates that the acid peel solution comprises at least one physiological acid. Claim 18 indicates that the physiological acid is citric acid, ascorbic acid, or pyruvic acid. Citric acid (a fruit acid), and ascorbic acid (capable of being extracted from fruits), are alpha hydroxyacids (AHAs). Pyruvic acid is an alpha-keto acid. These physiological

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acids described in the claims are weak acids as are other naturally-occurring AHAs. AHAs are the mildest of the acid or chemical peels and are most widely used for skin exfoliation because of their effectiveness and the absence of toxicity. Other types of acid peels are the Beta-lift peels or the beta hydroxyacids (BHA). BHAs are effective in lifting the topmost layer of skin by "dissolving" the desmosomes which bind it to the underlying epidermis, triggering cell division (proliferation), skin cell production and shedding.. An example of a beta hydroxyacid used as an acid peel is salicylic acid. Salicylic acid, which is soluble in oil, can exfoliate oily skin more effectively than other acid peels. At times AHAs and BHAs are used in combination as exfoliants.

- 12. The physiologic acids or acid peels identified in the Mann passages quoted above, and claims 17 and 18 of Mann, act by accelerating the shedding or loosening of the topmost layers of the skin (stratum corneum or keratinized epithelium) by decreasing their cohesiveness. The most effective of the AHA peels is glycolic acid.
- 13. Any person skilled in this art would recognize that surface acting acid peels as disclosed in Mann do not cause "abrasion/damage/lesions/wounds" on skin, as stated in the April 17, 2008 Office Action. One cannot hurt dead cells. The acid peels that Mann describes affect the outermost portion of the epidermis or skin, which is made up primarily of about 15-20 layers of dead cells that lack nuclei. Acid peels do cause surface exfoliation by reducing cellular cohesiveness and/or by denaturing or fragmenting the cell adhesion proteins of the desmosome complex. The acid peel solution that Mann describes, as stated in the patent, increases the permeability of the skin to his hair regeneration composition, but in no way causes abrasion, damage, lesions and/or wounds on the skin.
- 14. All statements made herein of my own knowledge are true and all statements made on information and belief, are believed to be true. These statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

inaueru	7.28.08	
Jo-David Fine, M.D., M.P.H., FRCP	Date	

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## **Curriculum Vitae**

## Jo-David Fine, M.D., M.P.H., FRCP

## Present position and address:

Professor of Medicine (Dermatology) and Pediatrics, Vanderbilt University, Nashville, TN Head, National Epidermolysis Bullosa Registry, Nashville, TN

Division of Dermatology, Department of Medicine c/o VMG Patterson Dermatology 1900 Patterson Street
Suite 100
Nashville, TN 37203
(615) 329-0801
fax (615) 320-7055
e-mail: Jo-David.Fine@vanderbilt.edu; ProfMoose@aol.com

Birthplace/Date:	Louisville, Kentucky	April 9, 1950
Education:		
J.M. Atherton Hig	gh School (with honors), Louisville, Kentucky	9/65 - 6/68
Yale College. B	.S., Chemistry ("Intensive Degree" Major)	9/68 - 1/72
University of Ken	tucky College of Medicine. M.D. (with distinction)	8/72 - 6/76
University of Nor M.P.H., Epic	th Carolina at Chapel Hill, School of Public Health, lemiology	8/91 - 12/92
Postgraduate Trainin	g:	
Intern, Medic	Medical Center, Durham, North Carolina cine ant Resident, Medicine	7/76 - 6/77 7/77 - 6/78
Massachusetts Ge Resident, De	neral Hospital, Boston, MA., & Harvard Medical School, rmatology (Clinical Fellow, Harvard University)	7/78 - 6/80
Samuel Mose	ndation, Boston, MA., & Harvard Medical School, chella, M.D. (preceptor) ent, Dermatology (Clinical Fellow, Harvard University)	7/80 - 6/81
Dermatology	s of Health, National Cancer Institute, Branch, Bethesda, MD., Stephen Katz, M.D., Ph.D. (preceptor) f Fellow, Dermatology	7/81 - 6/83
of Medicine ( St. Thomas' I Visiting Prof	e of Dermatology, at Guy's, King's and St. Thomas' School (King's College London, University of London), Hospital, London, England essor (sabbatical), Dept. of Cell & Molecular Pathology, a.J.Eady, D.Sc. (Med.) FRCP, Dean - St. John's Institute	9/00 - 3/01
Academic Positions:	, , , , , , , , , , , , , , , , , , , ,	7,00 0,0.
University of Alabama	at Birmingham School of Medicine, Birmingham, AL.	7/1/83 – 7/1/90
Director	of Dermatology of Dermatologic Research t Professor	7/83 - 6/90 7/83 - 5/85

Associate Professor	5/85 - 6/90
UAB Comprehensive Cancer Center Associate Scientist	8/83 - 6/90
Birmingham Veterans Administration Medical Center Consultant, Dermatology Chief, Dermatology Section, Medical Service	8/83 - 12/83 1/84 - 6/90
UAB Institute of Dental Research Investigator & Co-Director, LM-EM-Histochemistry- Autoradiography Unit	9/84 - 2/88
UAB Multipurpose Arthritis Center Scientist	11/85 - 6/90
University of North Carolina at Chapel Hill, School of Medicine, Chapel Hill, NC	7/1/90 – 8/19/02
Department of Dermatology Associate Professor Professor Residency Program Director  Fayetteville Veterans Administration Medical Center Consultant, Dermatology	7/90 - 8/92 9/92 - 8/02 7/00 - 1/02 7/90 - 8/02
University of North Carolina at Chapel Hill, School of Public Health, Chapel Hill, NC	12/93- 8/02
Department of Epidemiology Adjunct Professor Clinical Professor	12/93 - 12/94 1/95 - 12/02
North Carolina State University, College of Veterinary Medicine, Raleigh, North Carolina	1994 - 12/02
Department of Clinical Sciences (formerly named Dept. of Companion Animal and Special Species Medicine) Adjunct Professor	Spring 94 - 12/02

# St. John's Institute of Dermatology at Guy's, King's and St. Thomas' School of Medicine (King's College London, University of London),

St. Thomas' Hospital, London, England

Dept. of Cell & Molecular Pathology Visiting Professor & Visiting Consultant in Dermatology

9/00 - 3/01

## University of Kentucky College of Medicine, Lexington, KY

12/02 - 9/04

## Department of Medicine

Professor of Medicine (Dermatology) - Voluntary Faculty

## Vanderbilt University School of Medicine, Nashville, TN

9/04 - present

Division of Dermatology, Department of Medicine Professor of Medicine (Dermatology)

Department of Pediatrics Professor of Pediatrics

VA Tennessee Valley Healthcare System, Nashville campus Consultant, Dermatology 12/04 - present

## Other Professional Positions:

<u>Dermatology Associates of Kentucky</u> Dermatologist (private practice) 9/02 - 9/04

## University, Hospital, & VA Committees & Administrative Roles (1983 - present):

## University of Alabama at Birmingham, Birmingham, AL

Scientific Advisory Committee, General Clinical Research Center Research & Development Subcommittee, Oncology "A" (Human Use Panel), Birmingham VAMC Cost Containment Committee, University of Alabama Hospital	1984 - 1986 1987 - 1988 1987 - 1990
Pharmacy and Therapeutics Committee, Univ. of AL Hospital	1989 - 1990
University of North Carolina at Chapel Hill, Chapel Hill, NC	
University-wide Committees:	
Faculty Council	7/93 - 6/96
Provost's Task Force on The University and Lifelong Learning	11/98 - 5/99
School of Medicine:	
Medical School Admissions Committee member	11/90 - 6/96
Out-of-State Applicant Subcommittee	6/94 - 6/96
Reapplicant Subcommittee	8/94 - 6/96
First & Second Year Course Directors' Committee	10/95 - 2/01
Syllabus Subcommittee	1999
Second Year Curriculum Evaluation Committee	1996
Alpha Omega Alpha Gamma Chapter (UNC-CH)	
Faculty Committee (for student membership selection)	1998
Department of Dermatology:	
Search Committee member, Wheeler Professorship in Dermatology	1991
Dermatology Residency Selection Committee	1990 - 2002
Subcommittee to Revise Second Yr Medical School Curriculum	1994 - 1995
Course Director, Second Year Medical School Dermatology Curriculum	1995 - 2001
Director, Dermatoepidemiology Fellowship Program	1998 - 2002
Medical Student Career Goal Advisor for Dept. of Dermatology	3/00 - 8/01
Program Director, Dermatology Residency Program	7/00 - 1/02
Head, Dermatology Clinical Trials Workgroup	8/01 - 8/02

## Vanderbilt University School of Medicine, Nashville, TN

North Carolina Memorial Hospital / UNC Hospitals: Pharmacy & Therapeutics Committee

Hearing Committee (ad hoc medical staff appointment grievance-based)

## **Division of Dermatology**:

Medical Director, VMG Patterson Street Dermatology Clinic	2004 - present
Dermatology Executive Committee	2/06 - present
Member, Electronic Medical Record Committee	2005
Dermatology Residency Selection Committee	2006 - present
Member, Excellence Practice Committee	10/06 - present

11/90 - 10/96

7/00

## **Hospital Appointments**

University of Alabama Hospitals, Birmingham, AL Attending Physician	1983 – 1990
Birmingham Veterans Administration Medical Center, Birmingham, AL (Attending Physician & Chief of Dermatology)	1983 - 1990
North Carolina Memorial Hospital & University of North Carolina Hospitals, Chapel Hill, NC (Attending Physician)	1990 – 2002
Fayetteville Veterans Administration Medical Center, Fayetteville, NC (Dermatology Consultant)	1990 – 2002
University of Kentucky Medical Center, Lexington, KY (Voluntary Faculty)	2002 – 2004
Saint Joseph HealthCare, Lexington, KY (Courtesy Staff) St. Joseph Hospital St. Joseph East Hospital	2002 – 2004
Central Baptist Hospital, Lexington, KY Courtesy Staff	2002 – 2004
Samaritan Hospital, Lexington, KY Active Staff	2002 – 2004
Cardinal Hill Hospital, Lexington, KY Consulting Staff	2002 – 2004
Meadowview Regional Medical Center, Maysville, KY Courtesy Staff	2002 – 2004
Georgetown Community Hospital, Georgetown, KY Courtesy Staff	2002 - 2004
Frankfort Regional Medical Center, Frankfort, KY Consulting Staff	2003 - 2004
Continuing Care, Lexington, KY (Active Staff)	2003 - 2004
Select Specialty Hospital, Lexington, KY (Active Staff)	2003 - 2004
Vanderbilt University Medical Center, Nashville, TN Attending Physician	2004 - present
VA Tennessee Valley Healthcare System, Nashville campus Attending Physician (WOC)	2005 - present

#### Academic Awards (Undergraduate):

National Science Foundation Undergraduate Summer Research Fellowship (Yale University, Dept. of Chemistry)	1971
Academic Awards (Medical School):	
Alpha Omega Alpha	1975
Department of Medicine Prize (highest class standing in Internal Medicine)	1976
Upjohn Achievement Award (overall highest class standing, clinical years)	1976
Student Research Award, First Place (first ever awarded to a freshman)	1973
NIGMS Medical Scientist Research Fellowship (1-F12-GM-56, 064-01)	1973
for M.DPh.D. in Biochemistry (first one approved for the Univ. of Kentucky	
but eventually not funded due to Nixon's massive FY 1974 budgetary cutbacks)	
Graduated with honors (with only 7 other medical students)	1976
Other Professional Awards or Recognitions:	
Other Processional Awards of Recognitions.	
Honorary fellowships or society memberships:	
Fellowship, American College of Physicians	1984
Membership, Southern Society for Clinical Investigation	1988
Membership, American Dermatological Association	1996
Fellowship, Royal College of Physicians (London)	2007
Other professional awards:	
Distinguished Service Award, Dystrophic Epidermolysis Bullosa	
Research Association of America	1984
New Investigator Research Award (R23), NIH / NIAMS	1985 - 1988
Midcareer Investigator Award for Patient-Oriented Research (K24),	
NIH / NIAMS (first one to be awarded in the field of Dermatology)	1999 - 2004 *
* returned to NIH in August 2002, of	lue to career change
Gold Triangle Award, American Academy of Dermatology	
Lifetime Achievement Award for contributions to the	
field of epidermolysis bullosa	July 2005
note of option mory and outlook	July 2005

Honorary Life Membership, Dystrophic Epidermolysis Bullosa Research Association of the United Kingdom / International (only the 2nd one awarded; 1st to an American)

December 2006

#### Teaching awards or recognitions:

Course director of highest rated specialty-based course within the 2nd Yr Medical School Curriculum (Univ. of North Carolina)

Spring 1996

Sophomore Basic Science Teaching Award (UNC School of Medicine) (Highest individual faculty teaching award given during the pre-clinical years)

August 1998

Teaching Excellence Award (UNC School of Medicine)

August 2000

#### Citation impact:

First author most often cited in the dermatological literature, 1982-1996 (per a 1998 impact study prepared by the editors of the Archives of Dermatology):

Stern RS & Arndt KA: Top cited authors in Dermatology. A citation study from 24 journals, 1982-1996. Arch Dermatol 135: 299-302, 1999.

also cited in Stern RS & Arndt KA: Classic and near-classic articles in the dermatologic literature. <u>Arch Dermatol</u> 135: 948-950, 1999.

One of the articles first authored in 1991 (J Am Acad Dermatol 24: 119-135, 1991) was the <u>sixth</u> most cited article in this journal from 1979 (founding issue) - 1995.

One of the articles first authored in 2000 (<u>J Am Acad Dermatol</u> 42: 1051-1066, 2000) was the <u>most highly</u> cited <u>JAAD</u> article during a 2.5 year citation window (2001 - mid 2003) (per Wiss K: The JAAD top ten list. <u>J Am Acad Dermatol</u> 52: 166-164, 2005)

## **Medical Specialty Board Status:**

National Board of Medical Examiners

Diplomate 1977

American Board of Internal Medicine

Diplomate 1980

American Board of Dermatology

Diplomate 1981

Board sub-certification in Dermatological Immunology / Diagnostic and Laboratory Immunology

Diplomate 1985

## Visiting Professorships and Major or Named Invited Lectureships:

1984	Visiting Professor	Tulane University
1985	Visiting Professor	Vanderbilt University
1986	Visiting Professor	Emory University
1987	Visiting Professor Guest Lecturer	State University of New York, Buffalo Harvard Medical School, Mass. General Hospital & Beth Israel Hospital
1988	Howard Fox Lecturer	New York University
1989	Visiting Professor Visiting Professor	Brown University Harvard Medical School, Mass. General Hospital & Beth Israel Hospital
	Guest Lecturer Guest Lecturer	St. John's Institute of Dermatology, London Imperial Cancer Research Fund, London
1990	Visiting Professor	Penn State University
1991	Guest Lecturer Distinguished Guest Lecturer	University of Tennessee, Memphis Wilford Hall USAF Medical Center
1992	Guest Lecturer Visiting Professor	Medical College of Virginia Univ TX Medical Branch, Galveston
1993	Julius Stone ADSAI Lecturer	Hawaii Dermatology Symposium
1994	Visiting Professor Grand Rounds (Peds) Grand Rounds (Derm)	Northwestern University Univ. of Minnesota Univ. of Minnesota
1995	First Robert Jackson Lecturer	University of Ottawa, Canada
1996	Guest Professor	University of South Florida
1998	Visiting Lecturer Visiting Professor	University of Florida St. John's Institute of Dermatology, London
2000	Guest Lecturer Guest Lecturer Visiting Professor (6 mo.) Guest Lecturer	Univ. of Sao Paulo, Brazil Medical College of Georgia St. John's Institute of Dermatology, London Imperial Cancer Research Fund, London
2001	Guest Lecturer Guest Lecturer	Univ. of Edinburgh, Scotland Guy's Hospital, London

2002	Guest Lecturer Proctor & Gamble Lecturer	Univ. of Texas at Houston University of Cincinnati
	Visiting Professor	Brown University
	Guest Lecturer	Duke University
	10th Bernice Fine Memorial Lecturer in Cutaneous Medicine	University of Louisville
2003	Invited Speaker	Ohio State University
2004	Visiting Professor Guest lecturer	Henry Ford Hospital Kansas University Medical Center
2005	Invited overseas speaker	The Royal Society (London)
2006	Visiting Professor Visiting Professor	Paracelsus Private Medical University, Salzburg SUNY Stony Brook
2008	Invited Lecturer	University of Dundee, Scotland

#### Lectureships and Visiting Professorships

#### By Academic Institution (excluding own affiliations)

University of Pennsylvania

Tulane University

Vanderbilt University

National Institutes of Health & National Library of Medicine

**Emory University** 

State University of New York, Buffalo

Harvard Medical School

Massachusetts General Hospital

Beth Israel Hospital

New York University

Southwestern Medical School

Imperial Cancer Research Fund Laboratories, London

Tufts University

Brown University

Louisiana State University

Pennsylvania State University

Duke University

Wilford Hall USAF Medical Center

University of Tennessee

McGill University

Jefferson Medical College

Medical College of Virginia

University of Texas Medical Branch, Galveston

University of Minnesota

Northwestern University

Bowman Gray School of Medicine, Wake Forest University

University of Ottawa

University of South Florida

University of Florida

Yale University

St. John's Institute of Dermatology

University of California at Davis

Medical College of Georgia

Sao Paulo University Hospital, Brazil

North Carolina State University

St. Thomas' Hospital (King's College-London & Univ. of London)

St. Bartholomew's Hospital & Royal London School of Medicine and Dentistry, London

University of Edinburgh

Guy's Hospital, London

University of Texas Health Sciences Center at Houston

University of Cincinnati

Women's College Hospital, University of Toronto

University of Louisville

Ohio State University

Institute of Child Health & Great Ormond Hospital for Children, London

Henry Ford Hospital

Kansas University Medical Center

Paracelsus Private Medical University, Salzburg, Austria

SUNY StonyBrook

University of Dundee

#### By Organization (excludes research presentations \*)

American Academy of Dermatology Dystrophic Epidermolysis Bullosa Research Association (DebRA) of America South Central Dermatological Congress Annual Symposium on the Biology of the Skin, Gleneden Beach, OR Nashville Dermatological Society Southeastern Dermatological Society Florida Society of Dermatology American Dermatologic Society for Allergy and Immunology New England Dermatologic Society World Congress of Dermatology (West Berlin; New York City) American Society for Dermatopathology Canadian Dermatological Association Boston Dermatological Society Louisiana Dermatological Society Memphis Dermatologic Society Florida West Coast Society of Dermatology American Academy of Veterinary Dermatology American Dermatological Association New Mexico Dermatological Society DEBRA International (UK; Austria) Society for Pediatric Dermatology British Epidermo-Epidermiology Society DebRA of Canada Central KY Dermatology Nurses Association Nashville Dermatology Society North Carolina Dermatology Association Kansas City Dermatological Society Montana Academy of Dermatology

Nashville Dermatology Nurses Association

Society for Investigative Dermatology (1982 - )
Southern Society for Investigative Dermatology (1984 - )
American Academy of Dermatology (1983 - )
American Federation for Clinical Research (1982 - )
American Society for Cell Biology (1986 - )
several international symposia on inherited EB:
London (1989; 2000; 2003); Philadelphia (1991; 1996);
Chapel Hill (1994); Salzburg (1998)

<sup>\*</sup> which have been given at meetings of the

#### All Major Invited Lectures and Professorships (1982 - present):

```
Guest lecturer, Univ. of Pennsylvania School of Medicine, Dept. of Dermatology, Philadelphia, PA, 12/82
Invited speaker, Pediatric Grand Rounds, UAB, Birmingham, AL, 8/83
Invited speaker, Pediatric Dermatology Symposium, American Academy of Dermatology, Chicago, IL, 12/83
Invited speaker, Medical Grand Rounds, UAB, Birmingham, AL, 1/84
Visiting professor, Tulane University, Dept. of Dermatology, New Orleans, 1/84
Invited speaker, Rheumatology Grand Rounds, UAB, Birmingham, AL, 11/84
Invited speaker, First National Conference, Dystrophic Epidermolysis Bullosa Research Association of America,
     Washington, D.C., 11/84
Invited speaker, South Central Dermatological Congress XVII, New Orleans, 2/85
Invited speaker & visiting professor, Nashville Dermatological Society and Vanderbilt University, Division of Dermatology,
Invited speaker, 35th Annual Symposium on the Biology of the Skin, Gleneden Beach, OR, 10/85
Invited speaker, Monoclonal Antibody Symposium, American Academy of Dermatology, Las Vegas, NV, 12/85
Invited speaker, Southeastern Dermatological Society annual meeting, Nashville, TN, 4/86
Invited speaker, Florida Society of Dermatology annual meeting, Jacksonville, FL, 5/86
Invited speaker, Institute of Dental Research, UAB, Birmingham, AL, 5/86
Invited speaker, National Conference on Epidermolysis Bullosa, National Library of Medicine, Bethesda, MD, 9/86
Invited speaker, American Dermatologic Society for Allergy & Immunology annual meeting, Orlando, FL, 9/86
Visiting professor, Emory University, Dept. of Dermatology, Atlanta, GA, 10/86
Invited speaker, Dystrophic Epidermolysis Bullosa Research Association of America annual meeting, New Orleans, LA,
Invited speaker, Advanced Immunology Course, American Academy of Dermatology, New Orleans, LA, 12/86
Invited speaker, Monoclonal Antibody Symposium, American Academy of Dermatology, New Orleans, LA, 12/86
Visiting professor, State University of New York at Buffalo, Depts. of Dermatology & Microbiology, Buffalo, NY, 2/87
Invited speaker, New England Dermatologic Society, Massachusetts General Hospital, Boston, MA, 3/87
Guest lecturer, Harvard Medical School - Beth Israel Hospital, Dept. of Dermatology, Boston, MA, 3/87
Invited speaker, Prenatal Diagnosis Symposium, World Congress of Dermatology, Berlin, 5/87
Invited speaker, Plastic Surgery Grand Rounds, UAB, Birmingham, AL, 9/87
Invited speaker, American Society for Dermatopathology annual meeting, San Antonio, TX, 12/87
Invited speaker, Dystrophic Epidermolysis Bullosa Research Association of America annual meeting, San Antonio, TX,
Invited speaker, Monoclonal Antibody Symposium, American Academy of Dermatology,
    San Antonio, TX, 12/87
Invited speaker, Pediatric Grand Rounds, UAB, Birmingham, AL, 12/87
Howard Fox Lecturer, New York University School of Medicine, Dept. of Dermatology,
    New York, NY, 1/88
Invited speaker, Dept. of Medical Genetics, UAB, Birmingham, AL, 1/88
Invited speaker, Southwestern Medical School, Univ. of TX Health Sciences Center at Dallas, 1/88
Invited speaker, Southwestern Medical School, Univ. of TX Health Sciences Center at Dallas, 3/88
Invited speaker, Univ. of North Carolina School of Medicine, Dept. of Dermatology,
    Chapel Hill, NC, 4/88
Invited speaker, Canadian Dermatological Association annual meeting, Banff, Alberta, Canada, 6/88
Invited speaker, Neonatal/Obstetrics & Gynecology Grand Rounds, UAB, Birmingham, AL, 9/88
Invited speaker, Advanced Immunology, Immunodermatology, and Monoclonal Antibody Symposia, American Academy of
    Dermatology, Washington, DC, 12/88
Invited speaker, International Epidermolysis Bullosa Symposium, London, UK, 1/89
Invited speaker, Imperial Cancer Research Fund Laboratories, London, UK, 1/89
Invited speaker, St. John's Institute of Dermatology, London, UK, 1/89
Invited speaker, Tufts Univ. School of Medicine & New England Medical Center, Boston, MA, 3/89
Visiting professor, Brown University School of Medicine, Div. of Dermatology, Providence, RI, 5/89
Invited speaker, Univ. of North Carolina School of Medicine, Dept. of Dermatology, Chapel Hill, NC, 7/89
Invited speaker, International Update on Dermatology and Dermatopathology, Brighton, UK, 9/89
Visiting professor, Harvard Medical School - Massachusetts General Hospital & Beth Israel Hospital, Boston, MA, 10/89
Invited speaker, Boston Dermatological Society, Boston, MA, 10/89
Invited speaker, Louisiana State University School of Medicine, Department of Dermatology, New Orleans, LA, 11/89
Guest speaker, Louisiana Dermatological Society annual meeting, New Orleans, LA, 11/89
Invited speaker, American Society for Dermatopathology annual meeting, San Francisco, CA, 11/89
Visiting professor, Pennsylvania State University School of Medicine, Dept. of Dermatology, Hershey, PA, 4/90
Invited speaker, Westwood Conference on Clinical Dermatology, Hilton Head, SC, 10/90
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Invited speaker, Duke University Medical Center, Department of Dermatology, Durham, NC, 11/90

Visiting consultant and distinguished guest lecturer, Department of Dermatology, Wilford Hall USAF Medical Center, Lackland AFB, San Antonio, TX, 1/91

Visiting professor, University of Tennessee School of Medicine, Dept. of Dermatology, Memphis, TN, 3/91

Guest speaker, Memphis Dermatologic Society, Memphis, TN, 3/91

Guest lecturer, McGill University, Faculty of Medicine, Department of Medicine, Sir Mortimer B. Davis - Jewish General Hospital, Montreal, Canada, 7/91

Invited speaker, International Symposium on Epidermolysis Bullosa, Jefferson Medical College, Philadelphia, PA, 10/91 Invited speaker, Genetics and Genodermatoses course, American Academy of Dermatology annual meeting, Dallas, TX, 12/91

Invited participant, Workshop on Clinical Trials in Skin Diseases, National Institutes of Health / National Institute of Arthritis, Musculoskeletal; and Skin Diseases, Bethesda, MD, 1/92

Guest lecturer, Medical College of Virginia, Department of Dermatology, Richmond, VA, 3/92

Visiting professor, University of Texas Medical Branch, Department of Dermatology, Galveston, TX, 1992

Invited speaker, workshops on Epidermolysis Bullosa, Diseases of Skin Basement Membrane, and Prenatal Diagnosis, World Congress of Dermatology, New York City, 6/92

Invited faculty member, Research Methods in Clinical Research course (2 wk), Univ. of North Carolina at Chapel Hill, 7/92 Invited speaker, Genetics and Genodermatoses course, American Academy of Dermatology annual meeting, San Francisco, CA, 12/92

Julius Stone ADSAI Lecturer, Hawaii Dermatology Seminar, Hawaii, 2/93

Invited speaker, Scientific Workshop on the Epidemiology of Skin Diseases, National Institutes of Health / National Institute of Arthritis, Musculoskeletal, and Skin Diseases, Bethesda, MD, 3/93

Invited speaker, National Conference of the Dystrophic Epidermolysis Bullosa Research Association of America, Detroit, MI, 8/93

Invited speaker, Genetics and Genodermatoses course, American Academy of Dermatology annual meeting, Washington, DC, 12/93

Invited speaker, Departments of Pediatrics (Grand Rounds), University of Minnesota, Minneapolis, MN, 3/94

Invited speaker, Department of Dermatology, University of Minnesota, Minneapolis, MN, 3/94

Invited speaker, Duke University Medical Center, Division of Dermatology, Department of Medicine, Durham, NC, 3/94 Speaker and Program Director, International Symposium on Epidermolysis Bullosa, Chapel Hill, NC, 4/94

Visiting Professor, Department of Dermatology, Northwestern University Medical School and Children's Memorial Hospital, Chicago, IL, 4/94

Invited speaker, Bowman Gray School of Medicine, Wake Forest University, Department of Dermatology, Winston-Salem, NC, 1/95

Invited speaker, Genetics and Genodermatoses course, American Academy of Dermatology annual meeting, New Orleans, LA, 2/95

First Robert Jackson Lecturer, Division of Dermatology, University of Ottawa, Ottawa, Canada, 4/95

Invited participant, National Skin Diseases Data Workgroup meeting, National Institute of Arthritis and Musculoskeletal and Skin Diseases, Bethesda, MD, 9/95 & 2/96

Invited speaker, Southeastern Consortium for Dermatology, Chapel Hill, NC, 10/95

Invited speaker, National Conference of the Dystrophic Epidermolysis Bullosa Research Association of America, Houston, TX, 11/95

Invited speaker, Preparation for Recertification Course, American Academy of Dermatology annual meeting, Washington, DC, 2/96

Guest professor, University of South Florida College of Medicine, Department of Dermatology, Tampa, FL, 3/96

Invited speaker, Florida West Coast Society of Dermatology, Tampa, FL, 3/96

Invited speaker, Symposium on EB, Jefferson Medical College, Philadelphia, PA, 4/96

Invited speaker, Preparation for Recertification Course, American Academy of Dermatology annual meeting, San Francisco, CA, 3/97

Invited speaker, American Academy of Veterinary Dermatology annual meeting, Nashville, TN, 4/97

Guest speaker, New Mexico Dermatological Society, Albequerque, NM, 4/97

Speaker and scientific program chairman, Dystrophic Epidermolysis Bullosa Research Association of America National Conference '97, Chapel Hill, NC, 8/97

Guest speaker, Department of Dermatology, Vanderbilt University School of Medicine, Nashville, TN, 1/98

Invited speaker, DEBRA International Meeting 1998, Salzburg, Austria, 5/98

Invited speaker, Satellite Symposium on Hereditary and Acquired Bullous Dermatoses of the International Investigative Dermatology 1998 Meeting, Salzburg, Austria, 5/98

Visiting lecturer, University of Florida College of Medicine, Division of Dermatology, Gainesville, FL, 6/98

Invited speaker, Department of Dermatology, Yale University School of Medicine, New Haven, CT, 11/98

Visiting professor, St. Thomas' Hospital and St. John's Institute of Dermatology, London, UK, 12/98

Invited speaker, Rheumatology Grand Rounds, University of North Carolina, 1/99

Invited speaker, Department of Dermatology, University of Texas Medical Branch at Galveston, 4/99

Co-Chair, Second International EB Consensus Meeting on Diagnosis and Classification, Chicago, IL, 5/99

Invited participant, Consensus Meeting on Cicatricial Pemphigoid, Northwestern Univ., Chicago, IL, 5/99

Invited speaker, Department of Dermatology, University of California at Davis, Sacremento, CA, 5/99

Invited participant, National Skin Diseases Data Workgroup meeting, National Institute of Arthritis and Musculoskeletal and Skin Diseases, Rockville, MD, 6/99

Invited participant, NHANES Dermatology Workshop, Center for Disease Control and Prevention, National Center for Health Statistics, Rockville, MD, 6/99

Guest speaker, Society of Pediatric Dermatology annual meeting, Traverse City, MI, 7/99

Invited speaker and scientific program co-chairman, national meeting of the Dystrophic Epidermolysis Bullosa Research Association of America, Torrance, CA, 8/99

Invited participant, symposium on "Epidemiology and Health Services Research - Prospects for Development in Skin Diseases," co-sponsored by the Carl J. Herzog Foundation and the National Institute of Arthritis and Musculoskeletal and Skin Diseases, Bethesda, MD, 9/99

Invited participant and organizing committee member, International EB Research Visioning and Consensus Meeting, cosponsored by DebRA-Europe and DebRA of America, Newark, NJ, 10/99

Invited speaker, Division of Dermatology, Duke University Medical Center, Durham, NC, 12/99

Guest speaker, Division of Dermatology, Medical College of Georgia, and Augusta Dermatological Society, Augusta, GA, 2/00

Guest speaker, Department of Dermatology, Sao Paulo University Hospital, and "Il Journada Dermatólogica do HC-FMUSP," Sao Paulo, Brazil, 4/00

Invited speaker, Dermatology Symposium, North Carolina State University College of Veterinary Medicine, Raleigh, NC, 6/00

Invited speaker, EB 2000 International Symposium, London, England, 9/00

Guest speaker, Centre for Cutaneous Research, St. Bartholomew's and the Royal London School of Medicine and Dentistry, London, England, 11/00

Guest lecturer, St. John's Institute of Dermatology, London, England, 12/00

Visiting Professor & Visiting Consultant in Dermatology, Department of Cellular and Molecular Pathology, St. John's Institute of Dermatology; Guy's, King's, and St. Thomas' Medical School; and King's College - London, London, England, 9/00 - 3/01

Guest speaker, Department of Dermatology, University of Edinburgh, Scotland, 2/01

Invited speaker, British Epidermo-Epidemiology Society annual meeting, London, 3/01

Invited speaker, Department of Public Health Services, Guy's Hospital, London, England, 3/01

Invited speaker and organizing committee member, national meeting of DebRA-US, Philadelphia, PA, 11/01

Guest lecturer, Department of Dermatology, University of Texas Health Sciences Center at Houston, Houston, TX, 1/02

Proctor and Gamble Lecturer, Department of Dermatology, Univ. of Cincinnati, 2/02

Visiting Professor, Department of Dermatology, Brown University, Providence, RI, 4/02

Guest lecturer, Division of Dermatology, Duke University Medical Center, Durham, NC, 5/02

Keynote speaker, DebRA-Canada annual meeting, Women's College Hospital, Toronto, Canada, 6/02

10<sup>th</sup> Bernice Fine Lecturer in Cutaneous Medicine, University of Louisville School of Medicine, Louisville, KY, 12/02 Invited speaker, Robin Eady Festschrift, King's College London & St. John's Institute of Dermatology, London, UK, 4/03 Invited speaker, Division of Dermatology, University of Louisville School of Medicine, Louisville, KY, 4/03

Invited speaker, Department of Medicine, Ohio State University, 7/03

Invited speaker, Division of Dermatology, University of Louisville School of Medicine, Louisville, KY, 9/03

Invited speaker and Co-Chair, "Clinical Management of Children and Adults with Epidermolysis Bullosa: A

Multidisciplinary International Symposium", Institute of Child Health and the Great Ormond Street Hospital for Children NHS Trust, London, UK, 10/03

Invited speaker, North Carolina Dermatology Association winter meeting, Pinehurst, NC, 1/04

Invited speaker, annual meeting of the Association for Proficiency in Skin Immunopathology, held in conjunction with the American Academy of Dermatology, Washington, DC, 2/04

Guest speaker, Nashville Dermatology Society and Vanderbilt University Division of Dermatology, 5/04

Invited speaker, Division of Dermatology, University of Louisville School of Medicine, Louisville, KY, 5/04

Guest speaker, Grand Rounds, Department of Dermatology, Henry Ford Hospital, Detroit, MI, 6/04

Invited speaker, Division of Dermatology, University of Louisville School of Medicine, Louisville, KY, 8/04

Invited speaker, Kansas City Dermatological Society, Kansas City, KS, 11/04

Invited speaker, Dept of Pediatrics, Vanderbilt University School of Medicine, Nashville, TN, 1/05

Invited speaker, Division of Dermatology, University of Louisville School of Medicine, Louisville, KY, 8/05

Invited overseas speaker, Keratin and Genodermatoses Symposium, Royal Society (London), London, UK, 9/05

Invited speaker, Medical Grand Rounds, Vanderbilt University School of Medicine, Nashville, TN, 10/05

Invited speaker, Division of Pediatric Gastroenterology, Vanderbilt University School of Medicine, Nashville, TN, 10/05

Invited speaker, Montana Academy of Dermatology, Big Sky, MT, 1/06

Invited speaker, Nashville Dermatology Nurses Association, Nashville, TN, 4/06

Visiting Professor, Department of Dermatology, Paracelsus Private Medical University, Salzburg, Austria, May 15-25, 2006 Invited speaker and conference co-organizer, DebRA of America National Patient Care Conference, Nashville, TN, 6/06 Visiting Professor, Department of Dermatology, SUNY StonyBrook, 10/06

Invited Speaker, 1st International Symposium on Thymosins in Health and Disease, George Washington University, Washington, DC, 3/07

Chair, Third International EB Consensus Meeting on Diagnosis and Classification, Vienna, Austria, 5/07 Invited lecturer, Division of Dermatology, University of Louisville School of Medicine, 2/08 Invited speaker, EB and Cancer Symposium, University of Dundee, Dundee, Scotland, 3/08

## **Professional Societies:**

Medical:	
Alpha Omega Alpha Honor Medical Society	1975
American College of Physicians (Fellow)	1984
American Academy of Dermatology (Fellow)	1981
American Dermatological Association	1996
American Federation for Clinical Research	
American Dermatologic Society for Allergy and Immunology	
Board of Directors	1986 - 1987
Royal Society of Medicine (London) (Overseas Fellow)	1993
Member, Section on Dermatology	2001
Medical Dermatology Society	
Dermatology Foundation	
International Society of Dermatology (inactive)	
Southeastern Dermatological Association (inactive)	
Lexington Medical Society (inactive)	
Kentucky Medical Association (inactive)	
Kentucky Dermatological Society (inactive)	
Central Kentucky Dermatologic Association (inactive)	2004
Tennessee Dermatology Society	2004
Nashville Dermatology Society	2004
American Contact Dermatitis Society	2006
Royal College of Physicians (London) (Fellow)	2007
Medical Research:	
Society for Investigative Dermatology (SID):	1983 - present
Secretary-Treasurer, Southern SID	1985 - 1986
Vice-President, Southern SID	1986 - 1987
President, Southern SID	1987 - 1988
Southern Society for Clinical Investigation	1988
Dystrophic Epidermolysis Bullosa Research Association (DebRA) of America	
Scientific Advisory Board	1985 - present
Board of Trustees	1989 - 2007
DebRA of the United Kingdom and Europe	
International Review Board (research proposals)	1998 - present
Japanese Society for Investigative Dermatology, Overseas Member	1994 - 2002
Association for Patient-Oriented Research	2002-2005
Epidemiological:	
International Dermatoepidemiology Association	
Chair, Membership and Nominations Committee	1996 - 1997
American Public Health Association	1330 1337
American College of Epidemiology	
Other Scientific:	
American Society for Cell Biology (FASEB) (inactive)	
American Association of Immunologists (inactive)	
Society for Mucosal Immunology (inactive)	
Alabama Dermatological Society (inactive)	
North Carolina Dermatology Society (inactive) National Association of Veterans Administration Dermatologists (inactive)	
National Association of Veteralis Administration Definatologists (mactive)	
er Professional Activities:	
A. National organizations	
American Academy of Dermatology:	
Member, Task Force on Immunopathology	1984 - 1986
Member, Task Force on Genetics	1989 - 1992
Member, Committee on NIAMS Liason	1990 - 1992
Member & Judge, Scientific Program Committee, Residents and	.,,,

## Dystrophic Epidermolysis Bullosa Research Association of America, Inc.

(D.E.B.R.A. of America, New York, NY):

Scientific Advisory Board Research Goals Committee	1985 - present 1988 - 1989
Grants and Scientific Review Committee	1989 - 1990, and
	1996 -2007
Board of Trustees	1989 - 2007
Long Term Strategic Planning Committee	1992 - 1995
Scientific Program Chairman, '97 National Meeting	1997
Scientific Program Co-Chairman, '99 National Meeting	1999
Organizing Committee member, Visioning / Consensus Meeting	1999
Program Committee member, '06 National Meeting	2005 - 2006

## National Epidermolysis Bullosa Registry (NEBR), NIH / NIAMS:

1986 - present
1992 - present
1988 - present
1986 - 1997
1992 - present

## National Institutes of Health (NIH):

NIAMS National Skin Diseases Data Workgroup, member	1995 - present
NHANES Dermatology Workgroup, member	3/98 - present
NIH Advisory Committee (Freedom of Information Act/A-110)	•
regarding the OMB A110 regulation on public accessibility to	
federally funded data	1999
·	

## Epidermolysis Bullosa Medical Research Foundation (EBMRF, Provo, UT):

Scientific Advisory Board	1997 – present
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## National Alopecia Areata Registry, NIH / NIAMS:

Advisory Committee	2000 – present
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#### B. International organizations

## Dystrophic Epidermolysis Bullosa Research Association of the United Kingdom and Europe (D.E.B.R.A.-U.K./International, based in London, England):

International Grant Review Board for the Medical and Scientific	
Advisory Panel (1st American member so appointed)	
MSAP member	1998 - present
Member, Clinical Grants Review Subpanel	2005 - present
Vice-Chair	2005 - 2008
Chair	2008 - present
EB Skin Cancer Task Force member	2006 - present

## International Dermatoepidemiology Society:

## C. Study section / peer review activities

## 1. National

a.	National	Institutes	of Health

Member, Ad Hoc Special Study Section, NIH General Medicine A-2	9/86
Reviewer and participant, NIAMS site visit, program project grant, Jefferson Medical College, Philadelphia	3/87
Chairman, NIAMS site visit, program project grant, Dept. of Dermatology, University of Pennsylvania	6/88
Reviewer and participant, NIAMS supplemental application to funded program project grant (Jefferson Medical College)	12/90
Member and reviewer, Ad Hoc Special Study Section, NIAMS	3/91
Reviewer and participant, NIAMS site visit, program project grant, Jefferson Medical College, Philadelphia	4/92
Reviewer, NIAMS Ad Hoc Special Study Section (Rare Disease Registry Contracts, RFA-003), Bethesda, MD	5/94
Ad hoc reviewer, NCI Epidemiology and Disease Control Study Section, Subcommittee 2	10/96
Ad hoc reviewer, NIDR Oral Biology and Medicine-1 (OBM-1) Study Section	10/98
Member, NIAMS Ad Hoc Special Study Section (Multipurpose Clinical Research Centers)	7/99
Member, NIAMS Ad Hoc Special Study Section (K23 & K24 Career Development Awards)	10/99
Ad hoc reviewer, NCI Epidemiology and Disease Control Study Section, Subcommittee 2 (EDC-2)	12/99
b. Veterans Administration	
Outside Reviewer, Merit Review Proposals	Spring 1985 Fall 1986 Spring 1989 Fall 1994
c. Private Foundations (United States)	
Grant reviewer, March of Dimes Birth Defects Foundation	10/87
Grant reviewer, National Psoriasis Foundation	12/93

## 2. International

1989 - present

Grant reviewer, Dystrophic Epidermolysis Bullosa Research

Association (D.E.B.R.A.) of America

	Grant reviewer, Swiss National Science Foundation	5/91		
	Grant reviewer, The Wellcome Trust, London, UK	9/95; 4/98; 3/99; 4/03		
	Grant reviewer, Special Trustees for St. Thomas' Hospital, London, UK	2/98		
	Committee member, International Review Board (for grant proposals), D.E.B.R.AU.K./Europe, London, England	6/98 – present (twice yearly)		
	British Skin Foundation grants referee	2001		
	German Federal Ministry for Education and Research, Bonn, Germany	5/02, 5/08		
3.	Local (Institutional)			
	Reviewer (grants), UAB Comprehensive Cancer Center	9/86		
4.	Other			
	Reviewer, Resident/Fellow Award, Archives of Dermatology	1993 - 96		
	Reviewer (for abstract selection at annual regional meeting), Southern Society for Investigative Dermatology	1985 - 88		
	Reviewer (for abstract selection at annual national meeting), Society for Investigative Dermatology	1993, 1995		
	Reviewer (for abstract selection at annual national meeting), International Dermatoepidemiology Association	1996		
D. Editorial activities				
1.	Journals			
	Deputy Editor, <u>Journal of Investigative Dermatology</u> Editorial Board member, <u>Clinical and Experimental Dermatology</u> Editorial Board member, <u>Journal of the American Academy of</u>	1992 - 93 1994 - 98		
	Dermatology	2003 - 08		
2	Rooks			

## 2. Books

Section Editor (Cutaneous Biology/Oncogenesis), Cutaneous Surgery, 1986

Editor, Bullous Diseases (Igaku-Shoin Medical Publishers), 1993

Editor-in-Chief, Epidermolysis Bullosa: Clinical, Epidemiologic, and Laboratory Advances, and the Findings of the National Epidermolysis Bullosa Registry. Johns Hopkins University Press, May 1999

Co-Editor and Author, *Life with Epidermolysis Bullosa: Etiology, Diagnosis, and Multidisciplinary Care and Therap,y* Springer Verlag GmbH, Wien New York, 2008 (in press).

## 3. Other

Contributor, Dermatology Lexicon Project

2004 - present

## E. Reviewer (medical and scientific journals)

Archives of Internal Medicine	1982 - present
Journal of Investigative Dermatology	1983 - present
Archives of Dermatology	1984 - present
Journal of American Academy of Dermatology	1984 - present
Journal of Oral Pathology	1984 - present
Archives of Pathology & Laboratory Medicine	1984 - present
Arthritis and Rheumatism	1985 - present
American Journal of Medical Sciences	1985 - present
Collagen and Related Research	1985 - present
Laboratory Investigation	1986 - present
American Journal of Medicine	1986 - present
Pediatric Dermatology	1986 - present
American Journal of Kidney Diseases	1987 - present
Journal of Immunology	1987 - present
American Journal of Dermatopathology	1988 - present
Journal of Clinical Investigation	1989 - present
New England Journal of Medicine	1990 - present
British Journal of Dermatology	1991 - present
American Journal of Hematology	1991 - present
Journal of Cutaneous Pathology	1991 - present
Clinical and Experimental Dermatology	1993 - present
Journal of Dermatological Science	1993 - present
Archives of Dermatological Research	1993 - present
Lancet	1995 - present
Journal of Histochemistry and Cytochemistry	1997 - present
Journal of Cutaneous Medicine and Surgery	1998 - present
American Journal of Human Genetics	1999 – present
Acta Dermato-Venereologica	2002 - present
Journal of the European Academy of Dermatology & Venereology	2003 - present
Human Genetics	2004 - present
Pediatric Drugs	2007 - present
Indian Journal of Cancer	2008 - present

## F. University Teaching Responsibilities, 1983 - present

(excluding those directly related to the Dermatology Residency Program):

## University of Alabama at Birmingham (1983 - 1990):

## i. Department of Dermatology-based:

Second Year Medical School Curriculum, Dermatology Course Faculty member & lecturer

1983 - 1990

## University of North Carolina at Chapel Hill (1990 - 2002):

## 1. <u>Department of Dermatology-based</u>:

Second Year Medical School Curriculum, Dermatology Course Faculty member / lecturer

Spring 1991 - 2002

Course Director 1995 - 2001

#### 2. Other Formal University Teaching Activities:

#### a. School of Medicine

Faculty member, "Research Methods in Clinical Research for research fellows and chief residents," course co-sponsored by the Depts. of Medicine & Surgery

Summers 1992, 1994, 2001

Faculty member and seminar leader, Clinical Epidemiology and Preventive Medicine course (required of all 2nd year medical students); administered through the Dept. of Social Medicine, (~36 contact hrs/year)

1993 - 1998

## b. School of Public Health

Faculty member, Epidemiology 160 (Principles of Epidemiology) course, UNC School of Public Health

1994 - 1996

Lecturer, Epidemiology 276 (Occupational Epidemiology) course, UNC School of Public Health

1995, 1996

#### University of Louisville School of Medicine (2002 - present)

Lecturer, Division of Dermatology

12/02, 4/03, 9/03, 4/04, 8/04, 8/05, 2/08

#### G. Miscellaneous Professional Activities

#### 1. Administrative

## a. <u>Diagnostic Laboratory Activities</u>

Director and Founder, Laboratory of Immunodermatology, University of Alabama Health Services Foundation (regional diagnostic immunofluorescence laboratory)

1984 - 90

Co-Director and Founder, Laboratory of Immunodermatology, University of North Carolina at Chapel Hill (regional diagnostic immunofluorescence laboratory)

1990 - 2000

Director and Founder, Laboratory of Immundermatology, Vanderbilt University School of Medicine (regional diagnostic immunofluorescence laboratory)

2006 - present

Head and Founder, Contact Dermatitis and Patch Testing Clinic Vanderbilt University School of Medicine

2006 - present

#### b. <u>Training Program Director</u>

Program Director, 1st nationally approved residency training program in dermatologic immunology/diagnostic and laboratory

	immunology (via the American Board of Dermatology), Dept. of Dermatology, University of Alabama at Birmingham	1986 - 90
	Program Director, Clinical Dermatoepidemiology Fellowship, Univ. of North Carolina at Chapel Hill	1998 - 2002
	Program Director, D.E.B.R.A. Clinical Investigation Fellowship (for clinical research in inherited epidermolysis bullosa), Univ. of North Carolina at Chapel Hill	1999 - 2002
	Residency Program Director, Department of Dermatology, Univ. of North Carolina at Chapel Hill	7/00 - 1/02
c.	Research Project Director (Multicenter only)	
	National Epidermolysis Bullosa Registry: Southeastern Clinical Center (Principal Investigator) Data Coordinating Center (Principal Investigator) Overall Project Head	1986 - 1997 1992 - 2002 1992 - 2002
d.	Organizer and/or Chair, National and International Conferences	
	Program Chairman, Consensus Conference on Classification and Diagnostic Criteria for Inherited Epidermolysis Bullosa, Washington, DC	December 1988
	Program Director & Chairman of the Organizing Committee, International Symposium on Epidermolysis Bullosa, co-sponsored by the National Institutes of Health and the Univ. of North Carolina at Chapel Hill, Chapel Hill, NC	April 1994
	Scientific Program Chairman, 1997 National Meeting of the Dystrophic Epidermolysis Bullosa Research Association (D.E.B.R.A.) of America, Chapel Hill, NC	August 1997
	Program Co-Chairman, Second International Consensus Conference on Revised Classification and Diagnostic Criteria for Inherited Epidermolysis Bullosa, Chicago, IL	May 1999
	Scientific Program Co-Chairman, 1999 National Meeting of D.E.B.R.A. of America, Torrence, CA	August 1999
	Member, Organizing Committee, International Visioning and Consensus Meeting of D.E.B.R.A. of America and D.E.B.R.AEurope, Newark, NJ	October 1999
	Member, Steering Committee, Epidermolysis Bullosa 2000 Symposium, London, U.K. (held in September 2000)	1998 - 2000
	Scientific Program Organizing Committee member, 2001 National Meeting of D.E.B.R.A. of America, Philadelphia, PA	December 2001
	Co-Chairman, Scientific Workshop on Epidermolysis Bullosa, 20th World Congress of Dermatology, Paris, France	July 2002
	Scientific Program Co-Chairman, 2006 National Meeting of D.E.B.R.A. of America, Nashville, TN	June 2006
	Member, Organizing Committee, International Visioning and Consensus Meeting of D.E.B.R.A-International ("EB 2006"), Dublin, Ireland	October 3006

	Program Chair & Planning Committee, Third International Consensus Conference on Revised Classification and Diagnostic Criteria for Inherited Epidermolysis Bullosa, Vienna, Austria	May 2007
e.	Task force (national) and other academic committee activities	
	Task Force member, <u>Archives of Dermatology</u> Annual Trainee Award	1993 - 96
	Ph.D. dissertation committee member (Experimental Pharmacology), College of Veterinary Medicine, North Carolina State Univ.	1994 - 96
f.	Consultant: Blue Cross & Blue Shield of North Carolina	2000 - 2002
g.	Other professional administrative activities	
	Head, Dermatology Clinical Trials Workgroup, UNC-CH	8/01 - 8/02
	Selector of speakers for the annual Bernice Fine Lectureship in Cutaneous Medicine, Division of Dermatology, Univ. of Louisville School of Medicine (endowed by Dr. Fine's father, a dermatologist and Class of 1935 at the Univ. of Louisville School of Medicine)	1991 - present
	Director, Bullous Diseases Clinic, Vanderbilt	2004 - present
	Director, Contact Dermatitis Clinic, Vanderbilt	2006 - present
	Thymosan beta-4 clinical trial Core Review Committee member	2007 - present
<u>De</u>	velopment of educational teaching tools	
Cre	eator and author, <u>Dr. Cutis</u> , a prototypic interactive multimedia computer program for the teaching of basic dermatologic principles using the case study approach	Spring 1996
Со	author and editor, electronic syllabus for the second year medical school curriculum at UNC-CH	Spring 1998
Cre	cator and co-author (with Dr. Ho-Jin Kim) of an interactive multimedia computer program for the teaching of pediatric dermatology using the case study approach	1998
Co-	-author (with Prof. Robin Eady) of an interactive CD-ROM on inherited epidermolysis bullosa	2000
Co-	-author of "Questions and Answers about Epidermolysis Bullosa," an educational pamphlet produced and distributed by the National Institutes of Health (NIAMS) for use by patients and families of EB patients, lay organizations, and non-dermatologists, NIH Publication No. 03-7038 [www.niams.nih.gov/hiches.html	June 2003
	enidermolysis, bullosa html	nine 2003

2.

#### 3. Development of UNC Department of Dermatology manuals, syllabus, other

Editor & Co-Author, Second year medical school syllabus on dermatology, UNC-CH

Spring 1995

Creator of revised didactic curriculum for UNC Dermatology residency program

Spring 2001

Author of Dermatology Residency Handbook (for UNC Program)

Spring 2001

Co-author, UNC Dept. of Dermatology web site

Spring 2001

## 4. National EB Registry-related educational materials

Author of web site for Internet-accessible NEBR outcome data

2000, 2002

#### 5. International EB Registry (via Engelhorn Foundation, Luxembourg)

Author of web site for Internet-accessible patient enrollment and data collection

2001

#### 6. Other teaching activities

#### Galderma Pre-Board Review Course

2003 - present

Faculty member and lecturer ("Vasculitis, Connective Tissue Diseases, and Bullous Diseases") for a nationally-based yearly course for preparation for the American Board of Dermatology certification examination (attended by approx. 80% of all senior dermatology residents)

#### Dermatology Associates of KY

Lecturer, annual CME course for primary care physicians

2003

## 7. Other board memberships and consultantships

RegeneRx Biopharmaceuticals, Inc.

2004 - present

Member, Scientific and Medical Advisory Board

Contributor / Co-Editor on "Epidermolysis Bullosa" to the Dermatology Lexicon project

2004

## H. Medical Licensure:

Massachusetts (# 43461; currently inactive)	1978 - 1995
Maryland (# D26864; currently inactive)	1981 - 1983
Alabama (# 10869)	1983 - present
North Carolina (# 38938)	1990 – present
Kentucky (# 37227)	2002 - present
Ohio (#35-08-3856-F)	2004 - 2007
Virginia (# 0101236352)	2004 - 2008
Tennessee (#38923)	2004 - present

## I. Research Trainees, Students, and Postdoctoral Fellows:

<u>Name</u>	Sponsoring or Previous Institution	Dates (duration)
Elizabeth Spiers, M.D. (med. student)	Univ. of Texas, Galveston	1986 (3 months)
Joy Jester, M.D. (dermatol. resident)	Univ. of Colorado	1986 (6 months)
James Krell, M.D. (med. student)	Harvard Medical School	1988 (3 months)
Yuji Horiguchi, M.D., Ph.D. (postdoc.)	Kyoto University	1987 – 1989
Li Zeng, M.D. (postdoc. fellow)	China Medical University	1992 – 1995
Kathryn Riddelle, Ph.D. (postdoc.)	Northwestern University	1993 – 1995
Amy Stein, M.D. (clinical research fellow)	SUNY-Downstate / UNC-CH	2000 - 2001
Sarah Cash, M.D. (clin. research fellow)	West Virginia University	2001 – 2002
Joy De Leoz, M.D. (clin. research fellow)	Bicol Christian School of Medicine, Philippines	2001 – 2002
David Todd Devries, M.D. (medical student; Doris Duke Foundation Predoctoral Fellowship Program)	Univ. of North Carolina	2001 – 2002
Matthew Hall, M.D. (medical student)	Vanderbilt University	July 2005

## J. Community activities and miscellaneous professional awards:

#### College alumni-related

Yale Alumni Schools Committee (regional admissions committee for Yale College, responsible for the interviewing of all applicants from high schools within its designated catchment area):

Chapel Hill, NC: Committee member	1976-78, and 1993 - 1999
Director	1994 - 1999
Birmingham, AL: Committee member	1988 - 1990

#### Medical school alumni-related

Yale Club of Alabama, Vice-President

University of Kentucky Medical Alumni Association

Board Member (Representative, Class of 1976)

Committee member, Alumni Association Awards Committee

#### Miscellaneous citations

liste	ed in	American Men and Women of Science	1986; 1995-96; 2002
11	11	Best Doctors in America, 1992-93	
11	**	, " " ", 1994-95	
11	11	, " " ", 1998	
**	11	. " " ", 2001-02	
"	- 1	" " " 2005-06	
"	"	" " " ", 2007-08	
11	11	Best Doctors in America: Southeast Region, 1996-97	
11	11	International Who's Who in Medicine, 2nd ed.	1994
11	11	Who's Who in the South and Southwest, 25th ed.	1996
11	11	Who's Who in Medicine and Healthcare, 1st ed.	1997-98
17	11	Who's Who in Medicine and Healthcare, 2nd ed.	1999-2000
It	11	Who's Who in the World, 15th ed.	1998
**	"	Best Doctors in North Carolina (in Business North Carolina,	2002
		July 2002 issue)	
"	"	2000 Eminent Scientists of Today, 1st ed.	2003
11	11	Who's Who in America - 2006	2004
**	"	Who's Who in America - 2008	2008

the focus of an introductory article entitled "Prof. Jo-David Fine, the World Famous Dermatologist" in <u>Nishinihon Hifu</u> (<u>West Japanese Journal of Dermatology</u>) 50: 299-300, 1997 (prepared by a former Japanese postdoctoral fellow, now a department chair, at the request of the West Japanese Society of Dermatology)

1989 - 1990

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# B. Review Articles, Book Chapters (excluding those containing peer-reviewed original research), and Consensus Reports

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- 156. Fine JD, Johnson LB, Weiner M, Cash S, DeVries DT, DeLeoz J, Suchindran C: What have statistics taught us about EB? (accepted for presentation at the 20th World Congress of Dermatology, Paris, France, July 2002).
- DeVries DT, <u>Fine J-D</u>: Inadequate coverage of daily costs in patients with severe forms of epidermolysis bullosa: results of the National Epidermolysis Bullosa Registry. (presented at the First Doris Duke Clinical Research Fellowship Conference, St. Louis, MO, June 2002).
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- 159. <u>Fine JD</u>, Johnson LB, Weiner M: Major outcomes and inherited EB: overall and cause-specific cumulative risks of death. (presented at "Clinical Management of Children and Adults with Epidermolysis Bullosa: A Multidisciplinary International Symposium", London, England, October 2003).
- 160. Fine JD, Johnson LB, Weiner M: Cancer and inherited EB. (presented at "Clinical Management of Children and Adults with Epidermolysis Bullosa: A Multidisciplinary International Symposium", London, England, October 2003).
- 161. Fine JD: Structural integrity of the skin: clinicopathological and molecular correlates. (presented at the Winter 2004 meeting of the North Carolina Dermatological Association, Pinehurst, NC, January 2004).
- Rubin AI, Moran K, <u>Fine J-D</u>, Wargon O, Murrell DF: Urethral meatal stenosis in junctional epidermolysis bullosa. A rare complication effectively treated with a novel and simple modality. <u>Australasian J Dermatol</u> (presented, Spring 2006).
- 163. Fine J-D: Epidermolysis bullosa: a genetic disease of altered cell adhesion and wound healing, and the possible clinical utility of topically applied thymosin β4. (presented at the 1st International Symposium on Thymosins in Health and Disease, Washington, DC, 3/07).

## E. Books

- 1. <u>Fine J-D</u> (Editor): *Bullous Diseases*. In <u>Topics in Clinical Dermatology</u> series, Igaku-Shoin Medical Publishers, New York / Tokyo, 1993, 218 pp.
- 2. <u>Fine J-D</u> (Editor-in-Chief), Bauer EA, McGuire J, and Moshell A: *Epidermolysis Bullosa: Clinical, Epidemiologic, and Laboratory Advances, and the Findings of the National Epidermolysis Bullosa Registry.* Johns Hopkins University Press, Baltimore, May 1999, 520 pp.
- 3. <u>Fine J-D</u> and Hinter H, editors, *Life with Epidermolysis Bullosa: Etiology, Diagnosis, and Multidisciplinary Care and Therapy* Springer Verlag GmbH, Wien New York, 2008 (in press)

#### F. Theses

1. Fine J-D: Comparative analysis of the accuracy of four laboratory techniques for the diagnosis and subclassification of inherited epidermolysis bullosa: a study based on 575 consecutive cases initially examined by specialized immunohistochemistry from 1983 to 1992. Master's thesis in partial fulfillment of the requirements for the degree of Master of Public Health, Department of Epidemiology, University of North Carolina at Chapel, December 1992.

## G. Other Scholarly and Professional Works

- 1. <u>Fine J-D</u>, Arndt KA: Seborrheic dermatitis. Patient information pamphlet prepared for and distributed by the American Academy of Dermatology, 1984.
- 2. <u>Fine J-D</u>, Lee Charles: <u>Dr. Cutis</u>, a working prototype of an interactive multimedia computer program for the teaching of basic dermatologic principles using the case study approach, 1996 (utilized by UNC second year medical students, as part of their course requirements, 1996 2001).
- 3. <u>Fine J-D</u>, McGrath K: General guidelines to the routine management and care of inherited EB. Patient and physician oriented pamphlet prepared for and distributed by DebRA of America (to include electronic version via Internet web site), 2000.
- 4. <u>Fine J-D</u>: Internet web site for the National EB Registry, containing selected published data, University of North Carolina, 2000.
- 5. Co-author of "Living with EB" (an informational pamphlet produced by NIAMS for distribution to patients, lay audiences, and physicians), August 2002.
- 6. <u>Fine J-D</u>: Papulosquamous diseases. In <u>Pocket Diagnosis in Internal Medicine</u> (ed. by Mitchell MC Jr., for the Palm Pilot), PocketMedicine.com Inc., 2003.
- 7. <u>Fine JD</u>: Epidermolysis bullosa. BMJ Publishing Group BMJ In-Practice Web Site (2008). [a peer reviewed project by the <u>Br Med J</u>, linked with Epocrates drug database] [also listed under Review Articles]

### Research Funding

## Principal Investigator: Jo-David Fine

#### 1. Active:

RegeneRx Biopharmaceuticals. "Clinical trial on wound healing in epidermolysis bullosa with thymosin-beta-4". 11/05 - present. 2% effort. Total costs = \$50,000.

- 2. Submitted or pending applications: none
- 3. Applications in preparation: none

#### 4. Completed grants:

Dystrophic Epidermolysis Bullosa Research Association of America. "DEBRA nurse clinician / educator". 6/05 - 5/07. Total yearly costs = 56,358.

NIH (NIAMS), NO1 AR72233. "National Epidermolysis Bullosa Registry". 5/1/97 - 4/30/02. 25% effort. Total costs = \$2,173,012.

NIH (NIAMS), K24 AR02098 (Midcareer Investigator Award for Patient-Oriented Research). "Genotype correlates of inherited EB". 5/1/99 - 4/31/04. 50% effort. Direct costs (Yr 1) = \$88,522. (Priority Score = 124) [terminated at request of P.I. on 8/1/02, due to career change]

Englehorn Foundation for Rare Diseases (Luxembourg). "International Epidermolysis Bullosa Registry". 4/1/01 - 3/31/02. Total costs = \$30,000.

Roche Laboratories. "Chemoprevention of squamous cell carcinoma in recessive dystrophic epidermolysis bullosa with Accutane". 7/1/99 - 6/30/04. Medication to be provided for 200 participants for 5 years of clinical testing.) [terminated at request of P.I. on 8/1/02]

Dystrophic Epidermolysis Bullosa Research Association of America. "DEBRA Clinical Research Fellowship". 7/1/00 - 6/30/02. Total costs (yearly) = \$40,000.

Novartis Pharmaceuticals Corporation. "Unrestricted educational donation to the Medical Foundation of North Carolina for research on epidermolysis bullosa". 9/1/01. Total costs = \$50,000.

Food and Drug Administration (Orphan Diseases Program). FD-R-001796-01. "Accutane, cancer chemoprevention, and dystrophic EB" (Phase 1 trial). 10/1/00 - 9/30/02. 5% effort. Total costs = \$144,723 (one year, with no-cost extension for 2nd year).) [terminated at request of P.I. on 4/26/02]

Burroughs Wellcome Fund. "Burroughs Wellcome Fund Research Travel Grant -- Relationship of genotype to phenotypes and the risk of major outcomes in junctional and dystrophic epidermolysis bullosa". 9/1/00 - 2/28/01. Total costs = \$14,500.

NIH (NIAMS), NO1 AR22200. "National Epidermolysis Bullosa Registry - Clinical Coordinating Center". 5/1/92 - 4/30/97. Total costs = \$1,217,357.

NIH (NIAMS), NO1 AR22201. "National Epidermolysis Bullosa Registry - Clinical Site". 5/1/92 - 4/30/97. Total costs = \$952,705.

NIH (NIAMS), NO1 AM62271. "National Epidermolysis Bullosa Registry - Clinical Site". 9/24/86 - 9/23/91. Total costs = \$452,859.

NIH (NIAMS), 1 R13 AR42649. "International Symposium on Epidermolysis Bullosa". 4/25/94 - 4/26/94. Total direct costs = \$11,000.

NIH (NIAMS), 2 RO1 AR34861-06. "Skin basement membrane zone and epidermolysis bullosa". 7/1/91 - 6/30/94. Total costs = \$494,323.

NIH (NIAMS), 1 R23 AM34861-03 (New Investigator Research Award). "Monoclonal antibodies to skin basement membrane zone". 8/1/85 - 7/31/88. Total costs = \$144,999.

NIH (NIAMS), 5 RO1 AR36629-03. "Physiologic biomatrices and epidermolysis bullosa". 9/30/85 - 8/31/88. Total costs = \$377,500.

Veterans Administration Medical Research Service, Merit Review Award. "Characterization of basement membrane structural antigens in skin". 10/1/85 - 9/30/88. Total costs = \$109,396.

Veterans Administration Medical Research Service (RAGS Proposal). "Characterization of basement membrane zone antigens in human skin". 10/1/84 - 9/30/85. Total costs = \$23,300.

American Cyanamid Company. "Viprostol male pattern alopecia clinical trial". 1/1/87 - 9/1/88. Total costs = \$92,240.

Dreyfus Medical Foundation. "A study of the efficacy of dilantin in children with junctional epidermolysis bullosa" .6/1/85 - 5/31/86. Total costs = \$1,850.

Dermatology Foundation. "Determination of differences in cell membrane glycoproteins in skin from patients with epidermolysis bullosa simplex as previously defined by abnormal peanut agglutinin lectin binding". 1/1/85 - 12/31/95. Total costs = \$5,000.

## 5. <u>Unfunded proposals (recent):</u>

Food and Drug Administration (Orphan Diseases Program). "Accutane, cancer chemoprevention, and dystrophic EB" (Phase 2/3 trial). 10/1/01 - 9/30/04. 25% effort. Direct costs (Yr 1, \$295,000; total, \$872,003), Total costs (Yr 1, \$429,225; total, \$1,268,764).

NIH (NIAMS), RFP BAA-0002 (submitted 6/9/00). "Cutaneous Lymphoma Registry". 10% effort. 9/1/00 - 8/31/05. Total costs = \$2,339,476.

NIH (NIAMS), RFP BAA-0002 (submitted 6/9/00). "Pemphigus Registry" (LA Diaz, P.I.). 10% effort. 9/1/00 - 8/31/05. Annual costs (Yr 1 only) = \$381,759

### Principal Investigator: Other

- 1. Active: none
- 2. Pending: none

# 3. <u>Completed:</u>

Doris Duke Foundation. "Clinical Research Fellowship Program" (Paul Watkins, P.I.; J-D Fine, mentor). 7/1/01 – 6/30/02. Total costs (to mentor, excluding stipend to fellow) = \$5,000.

Centers for Disease Control and Prevention /Environmental Health. "Pfiesteria-related illness surveillance and prevention" (Christine Moe, P.I.; J-D Fine, consultant, 5% effort, one year only). 3/1/98 - 2/28/01. Total costs = \$981.960.

Centers for Disease Control and Prevention / Health Promotion and Disease Prevention Center (U48/CCU 409660). "Development and evaluation of a skin cancer education program for public health nurses" (Lorraine Johnson, P.I.; J-D Fine, Co-Investigator, 2% effort). 9/30/94 - 9/30/98. Total costs = \$304,381.